DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 5, 2014

Rhythmedix, LLC
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141813
Trade/Device Name: RhythmStar System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH
Dated: July 3, 2014
Received: July 7, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, MD.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141813

Device Name

RhythmStar System

Indications for Use *(Describe)*

The RhythmStar system is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional.
The data received from the RhythmStar device can be used by another device for arrhythmia analysis, reporting and signal measurements. The RhythmStar system is not intended to sound any alarms.
The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. RhythmStar is for prescription use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K141

Ken Skodacek for

Bram Zuckerman

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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RhythMedix™

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Submitted by	Rhythmedix, LLC Horizon Corporate Center 5000 Atrium Way, Suite 1 Mt. Laurel, NJ 08054
Contact	Stan Biletsky sbiletsky@rhythmedix.com
Establishment Registration Number	N/A
Date Prepared	June 20, 2014
Trade Name	RhythmStar System
Common Name	Mobile Cardiac Monitor
Device Classification (regulation)	870.2920 Telephone electrocardiograph transmitter and receiver.
Class	II
Product Code	DXH
Classification Panel	Cardiovascular
Equivalent Marketed Device(s) (Predicate device(s))	K131699, eMotion ECG Mobile, Mega Electronics Ltd K083535, Heartrak Smart ECAT, Universal Medical, Inc.
Device Description (abbreviated)	The RhythmStar system consists of the RhythmStar device and the server. The RhythmStar device is a portable, battery-powered, wireless cardiac monitor which may be worn by a patient to record ECG and activity level data for up to 30 consecutive days. The device can capture patient activated and auto-triggered events such as Bradycardia, Tachycardia, and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm. The device is capable to automatically deliver the data to the server. The data can be delivered to the server wirelessly via mobile network or via USB connection. A medical professional, using the server, can adjust and program the device configuration and auto-triggering parameters.
Intended Use	The RhythmStar system is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously

records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional.
The data received from the RhythmStar device can be used by another device for arrhythmia analysis, reporting and signal measurements. The RhythmStar system is not intended to sound any alarms.
The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. RhythmStar is for prescription use only.

Technological Characteristics

The RhythmStar device patient kit includes:

- RhythmStar monitor
- Patient ECG lead cable (3-lead cable included, 5-lead cable optional)
- 2 externally re-chargeable batteries
- Wall battery charger (the charger cannot be connected to the device)

The monitor consists of an analog ECG front end, accelerometer, MCU, flash data storage, RF modem for data transmission, LCD screen, and Record button. The server components facilitate data communication with the RhythmStar device, provide data storage, and present the data for evaluation by a medical professional.

There are known similarities between the new device and the predicate devices:

- All devices are small, lightweight ambulatory cardiac monitors.
- All devices use the same wireless technology to deliver data to a server.
- All devices are battery powered and have a rechargeable Li-Ion battery.
- The RhythmStar and Heartrak Smart ECAT (K083535), using a server, can adjust device programming parameters such as pre-post recording times and auto-triggering configuration.
- The RhythmStar and eMotion ECG Mobile (K131699) devices incorporate an accelerometer to capture activity level data related to patient motion and device orientation.
- All devices have Record button for manual event recordings and a user interface capabilities to indicate device status and mode of operation.
- The RhythmStar and Heartrak Smart ECAT (K083535) incorporate embedded ECG analysis algorithm to auto-

capture Bradycardia, Tachycardia and Atrial Fibrillation. The eMotion ECG Mobile (K131699) detects arrhythmia events on the server. All devices detect arrhythmia events between the signal acquisition point and the reviewer of the data.

- All devices have at least 2 ECG channels and 3-lead electrodes.
- All devices have identical or very similar Functional, Environmental and Electrical characteristics

There are known differences between the new device and the predicate devices that do not impact safety or effectiveness:

- Predicate devices use external RF component (cell phone) between ECG sensor and the server for long range data transmission and transmit ECG data to the cell phone communicator using a close range RF link such as Bluetooth connection. Essentially, the predicate devices utilize two different RF technologies (BT and Mobile Network) and two separate components – ECG sensor to collect ECG data and a wireless communicator (cell phone) to deliver the data to the server. The new device integrates a wireless modem module into a single unit design to improve reliability of the overall system, reduce risks related to delayed data delivery, improve patient compliance by reducing complexity of the device, and lower production costs. The RhythmStar uses the same wireless technology (Mobile Network) as the predicate devices to deliver data to the server and is therefore substantially equivalent to the predicates.
- Predicate devices can recharge the internal battery on-board. The new device utilizes batteries that are charged externally in a wall charger made by a third-party. This design eliminates any risks of electrical shock during charging because the charger cannot be connected to the device and the patient is never connected to the charger directly or indirectly. All devices use the same energy source – rechargeable Li-Ion battery and require the patient to recharge it and are therefore substantially equivalent.
- The new device supports USB connectivity in addition to being able to transmit data to the server via the mobile network. The predicate devices deliver data to the server via the mobile network only. The RhythmStar's ability to deliver and/or receive data to/from the server in more than one way addresses risks related to potential failures to deliver data wirelessly due to: wireless service unavailability,

wireless component malfunction, and issues that arise from misuse of the device. According to the RhythmStar System Requirements Specification, the physical design of the cable connector on the device makes it physically impossible to connect the RhythmStar to a USB or any other device while patient ECG lead cable is plugged-in. Adding USB capability in RhythmStar device does not introduce any new risks, change the intended use, or pose any questions concerning safety or effectiveness.

- There are several minor differences related to electrical and environmental characteristics between the new and predicate devices. All devices meet minimum requirements for the corresponding parameters as sited in AAMI-EC38/IEC 60601-2:47 standards for ambulatory arrhythmia monitoring and are therefore substantially equivalent.

Performance Testing (Bench, Animal, Clinical)

The following performance and safety tests have been passed successfully:

- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 60601-1:2005 3rd Edition, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007 3rd Edition, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-11:2010 Edition 1.0, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- ANSI/AAMI-EC 57:2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms.
- IEC 60601-2-25:2011 standard (Particular requirements for the basic safety and essential performance of electrocardiographs).
- IEC 60601-1-6:2010 Edition 3.0, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
- Biocompatibility testing of patient contacting materials according to ISO 10993.

	Bench test results verify that RhythmStar system can continuously record ECG signal, store ECG data in the device memory, and transmit manual or auto activated event recordings to the server via mobile network or USB connection for evaluation by a medical professional. Test results verify that all requirements were met and that the RhythmStar performs as designed.
Substantial Equivalence Rationale	The intended use, performance and technological characteristics of the RhythmStar system compared to the named predicate devices demonstrates that the RhythmStar is substantially equivalent to the predicates.
Conclusions	The analysis of the differences between RhythmStar and the predicate deices does not raise new questions of safety and effectiveness. Based on device performance test results, Rhythmedix determines that the RhythmStar system is safe, effective, performs within its design specifications, and is substantially equivalent to the predicate devices. The information in this 510(k) submission demonstrates that the RhythmStar system is substantially equivalent to the predicate devices, with respect to safety, effectiveness, and performance.